

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 28, 2007

MEMORANDUM

SUBJECT: Review of *"Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Gloved Hands Following Multiple Hand Press"*

FROM: Seyed Tadayon, Chemist *[Signature]*
Reregistration Branch 3
Health Effects Division (7509P)

THRU: Jeff Evans, Biologist *[Signature]*
Chemistry Exposure branch (CEB)
Health Effects Division (7509P)

TO: ~~████████████████████~~
Special Review and Reregistration Division (7508P)

DP Barcode: 336762

PC Code: 109701

MRID Number: 461886-19

Enclosed is a review of the MRID 461886-19 *"Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press"* submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to first determine the degree of transfer of pyrethrin (PY) and piperonyl butoxide (PBO) residue from previously untouched areas of treated carpet flooring as a function of multiple contacts using bare and gloved hands after a single application of an unidentified pre-fill batch fogger formulation containing 0.785% PY and 1.55% PBO as the active ingredients. Secondly, the study was to determine transfer of PY and PBO residues from the same contact area of treated carpet flooring as a function of multiple contacts using both bare and gloved hands.

Two sprayboom runs were performed on two separate days in order to generate sufficient treated carpet flooring sections. The application of the test product was applied using the sprayboom run to

obtain a desired deposition of $3.96 \mu\text{g}/\text{cm}^2$ of PY and $7.87 \mu\text{g}/\text{cm}^2$ of PBO onto the carpet flooring surfaces.

The deposition rate was calculated to be 122% of the target deposition rate for PY and 149% of the target deposition rate for PBO for the first application and 134% and 157% of the target deposition rate for PY and PBO, respectively, for the second application. Bare hand transfer residues for the different number of presses for each of the four rounds ranged from $0.118 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $3.69 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PY and from $0.184 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $7.08 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PBO. Glove transfer residues for the different number of presses for each of the four rounds ranged from $0.144 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $3.07 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PY and from $0.245 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $5.89 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PBO.

Concurrent laboratory control samples were prepared and run for the alpha cellulose coupons, the dressing sponges and the cotton gloves. The percent recoveries for alpha cellulose coupons ranged from 88% to 107% for PYI and from 68.1% to 111% for PBO, for dressing sponges 80% to 106% for PYI and from 84.4% to 109% for PBO and 74.4% to 114% for PYI and from 77.9% to 104% for PBO for cotton gloves.

Field Fortification recoveries using alpha cellulose coupons, the dressing sponges and the cotton gloves showed an overall average recoveries for PYI and for PBO were $85.9 \pm 9.3\%$ and $75.2 \pm 3.5\%$, $106 \pm 6.8\%$ for PYI and $103 \pm 4.9\%$ for PBO and $99.5 \pm 9.8\%$ for PYI and $102 \pm 4.4\%$ for PBO respectively.

The transfer of PY and PBO residues from treated carpet flooring to bare hands and cotton gloved hands following multiple presses on new or the same treated area was measured. The results of this study indicate that the amount of residue per press of both PY and PBO transferred from a carpet flooring surface to bare hands or cotton gloves following four rounds of 2 to 32 hand presses initially increased and then decreased as the number of presses increased. The residues of PY and PBO was highest in round 1 and then decreased with every successive round of presses (Table A).

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

Table A: Summary of PY and PBO Bare and gloved Hand Press Results on Carpet Flooring Following Multiple Presses

Rounds	# of Carpet Sections Pressed	Measured Residue (µg/sample) Bare Hand		Measured Residue (µg/sample) gloved Hand		Glove Surface Area (cm ²)	Residue by # of Presses (µg/cm ²) Bare Hand			Residue by # of Presses (µg/cm ²) Gloved Hand			% of Application by # of Presses Bare Hand		% of Application by # of Presses Gloved Hand		Residue per Press (µg/cm ²) Bare Hand		Residue per Press (µg/cm ²) Gloved Hand		% of Application per Press Bare Hand		% of Application per Press Gloved Hand	
		PYI	PBO	PYI	PBO		PYI	PY	PBO	PYI	PY	PBO	PY	PBO	PY	PBO	PY	PBO	PY	PBO	PY	PBO	PY	PBO
1	2	2.42	41.1	11.2	36.5	97.7	0.0229	0.235	0.421	0.115	0.204	0.374	4.42	3.42	4.22	3.19	0.118	0.210	0.102	0.187	2.21	1.71	2.11	1.60
	4	23.0	72.3	lost	lost	55.9	0.411	0.732	1.29	lost	lost	lost	13.8	10.5	lost	lost	0.183	0.323	lost	lost	3.44	2.63	lost	lost
	8	18.8	130	44.0	132	61.0	0.308	0.549	2.13	0.721	1.28	2.16	10.3	17.3	26.5	18.5	0.069	0.266	0.160	0.270	1.29	2.17	3.32	2.31
	16	86.0	314	83.9	255	89.2	0.964	1.72	3.52	0.941	1.67	2.86	32.3	28.6	34.6	24.4	0.107	0.220	0.105	0.179	2.02	1.79	2.16	1.53
	32	225	767	187	639	108.4	2.08	3.69	7.08	1.73	3.07	5.89	69.4	57.5	63.4	50.4	0.115	0.221	0.096	0.184	2.17	1.80	1.98	1.57
2	2	8.14	23.7	9.70	31.4	97.7	0.083	0.148	0.243	0.099	0.177	0.321	2.79	1.97	3.65	2.75	0.074	0.121	0.088	0.161	1.39	0.99	1.83	1.37
	4	12.9	36.8	21.3	68.4	55.9	0.231	0.411	0.658	0.381	0.678	1.22	7.72	5.35	14.0	10.5	0.103	0.165	0.170	0.306	1.93	1.34	3.50	2.61
	8	24.5	77.5	38.6	117	61.0	0.402	0.715	1.27	0.633	1.13	1.92	13.4	10.3	23.3	16.4	0.089	0.159	0.141	0.240	1.68	1.29	2.91	2.05
	16	58.7	194	82.3	243	89.2	0.658	1.17	2.17	0.923	1.64	2.72	22.0	17.7	33.9	23.3	0.073	0.136	0.103	0.170	1.38	1.11	2.12	1.46
	32	123	415	182	543	108.4	1.13	2.02	3.83	1.68	2.99	5.01	38.0	31.1	61.7	42.8	0.063	0.120	0.093	0.157	1.19	0.97	1.93	1.34
3	2	9.51	35.1	10.0	30.8	97.7	0.097	0.173	0.359	0.102	0.182	0.315	3.26	2.92	3.75	2.69	0.087	0.180	0.091	0.158	1.63	1.46	1.88	1.35
	4	9.36	29.9	16.3	47.5	55.9	0.167	0.298	0.535	0.292	0.519	0.850	5.60	4.35	10.7	7.26	0.075	0.134	0.130	0.212	1.40	1.09	2.68	1.82
	8	22.2	71.4	38.2	111	61.0	0.364	0.648	1.17	0.626	1.11	1.82	12.2	9.52	23.0	15.6	0.081	0.146	0.139	0.227	1.52	1.19	2.88	1.94
	16	53.1	164	73.7	220	89.2	0.595	1.06	1.84	0.826	1.47	2.47	19.9	14.9	30.4	21.1	0.066	0.115	0.092	0.154	1.24	0.93	1.90	1.32
	32	124	415	171	535	108.4	1.14	2.04	3.83	1.58	2.81	4.94	38.3	31.1	58.0	42.2	0.064	0.120	0.088	0.154	1.20	0.97	1.81	1.32
4	2	6.45	18.0	7.93	23.9	97.7	0.066	0.118	0.184	0.081	0.144	0.245	2.21	1.50	2.99	2.09	0.059	0.092	0.072	0.122	1.10	0.75	1.49	1.05
	4	9.33	29.6	12.2	34.8	55.9	0.167	0.297	0.530	0.218	0.388	0.623	5.58	4.31	8.03	5.32	0.074	0.132	0.097	0.156	1.40	1.08	2.01	1.33
	8	20.6	63.7	36.7	108	61.0	0.338	0.601	1.04	0.602	1.07	1.77	11.3	8.49	22.1	15.1	0.075	0.131	0.134	0.221	1.41	1.06	2.77	1.89
	16	47.9	149	65.7	205	89.2	0.537	0.956	1.67	0.737	1.31	2.30	18.0	13.6	27.1	19.6	0.060	0.104	0.082	0.144	1.12	0.85	1.69	1.23
	32	106	359	162	480	108.4	0.978	1.74	3.31	1.49	2.66	4.43	32.7	26.9	55.0	37.8	0.054	0.103	0.083	0.138	1.02	0.84	1.72	1.18



MEMORANDUM

TO: Margarita Collantes

FROM: Teri Schaeffer/Linda Phillips

DATE: March 12, 2004

SUBJECT: Review of "*Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses*" (Project #: 01-025-PY01)

This report reviews a study entitled "*Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses*." The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

Reviewers: Teri Schaeffer/Linda Phillips

Date: March 12, 2004

STUDY TYPE: Active Transfer; Carpet Flooring

TEST MATERIAL: An unidentified pre-fill batch fogger formulation containing 0.785% pyrethrin (CAS no. 8003-34-7) and 1.55% piperonyl butoxide (CAS no. 51-03-6) as the active ingredients was used.

SYNONYMS: Pyrethrin (PY) and Piperonyl Butoxide (PBO)

CITATION: Author/ Study Director: Sami Selim, Ph.D.
Title: *Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses*

Report Date: August 27, 2002
Testing Facility: Toxcon Health Sciences Research Centre Inc.
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Analytical Facility: Enviro-Test Laboratories/XENOS Division
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Identifying Codes: Toxcon Study Number: 01-025-PY01
Xenos Project Number: XEN02-10
Unpublished

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews the study “*Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses*” submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to first determine the degree of transfer of pyrethrin (PY) and piperonyl butoxide (PBO) residue from previously untouched areas of treated carpet flooring as a function of multiple contacts using bare and gloved hands after a single application of an unidentified pre-fill batch fogger formulation containing 0.785% PY and 1.55% PBO as the active ingredients. Secondly, the study was to determine transfer of PY and PBO residues from the same contact area of treated carpet flooring as a function of multiple contacts using both bare and gloved hands.

A test room was prepared with wooden platforms placed in the center of the room. Carpet flooring sections were placed on the platforms along with deposition coupons. Two sprayboom runs were performed on two separate days in order to generate sufficient treated carpet flooring sections. The application of the test product was applied using the sprayboom run to obtain a desired deposition of 3.96

ug/cm² of PY and 7.87 ug/cm² of PBO onto the carpet flooring surfaces. During the application, and for three hours after the application, the ventilation system in the room was turned off (with the dampers closed) to allow for deposition of airborne formulation onto the test surfaces. After the three hours, the dampers were opened for a 30 minute drying period. Following the 30 minute drying period the degree of transfer of PY and PBO was measured using the following methods: (1) multiple presses (2, 4, 8, 16, or 32 consecutive presses) of both bare and gloved hands on previously untouched treated carpet flooring sections (i.e., contact with 2, 4, 8, 12 or 32 treated tiles) and (2) multiple presses (2, 4, 8, 16, or 32 consecutive presses) on the same contact area of PY and PBO treated carpet flooring using both bare and gloved hands (i.e., contact with the same 2, 4, 8, 16, or 32 treated tiles as in round 1).

The achieved deposition rate was calculated by Versar to be 122% of the target deposition rate for PY and 149% of the target deposition rate for PBO for the March 12, 2002 application and 134% and 157% of the target deposition rate for PY and PBO, respectively, for the March 13, 2002 application. Bare hand transfer residues for the different number of presses for each of the four rounds ranged from 0.118 µg/cm² (4th round, after 2 presses) to 3.69 µg/cm² (1st round, after 32 presses) for PY and from 0.184 µg/cm² (4th round, after 2 presses) to 7.08 µg/cm² (1st round, after 32 presses) for PBO. Glove transfer residues for the different number of presses for each of the four rounds ranged from 0.144 µg/cm² (4th round, after 2 presses) to 3.07 µg/cm² (1st round, after 32 presses) for PY and from 0.245 µg/cm² (4th round, after 2 presses) to 5.89 µg/cm² (1st round, after 32 presses) for PBO.

The transfer of PY and PBO residues from treated carpet flooring to bare hands and cotton gloved hands following multiple presses on new or the same treated area was measured. The results of this study indicate that the amount of residue per press of both PY and PBO transferred from a carpet flooring surface to bare hands or cotton gloves following four rounds of 2 to 32 hand presses initially increased and then decreased as the number of presses increased. The residues of PY and PBO was highest in round 1 and then decreased with every successive round of presses.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

1. A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
2. The test product was not identified and a label was not provided.
3. Calibration procedures for the application equipment were not provided in the Study Report.
4. On page 18 of the Study Report, in the Methods section (IX), the study author listed 4 phases of the study. Phase III was said to be “the bare hand press exposure and the indoor roller transferability...” Indoor roller transferability was not a part of this study.
5. Table 1 on page 36 of the Study Report is titled “Assignment of Treatments and Treated Vinyl Flooring Sections for Bare and Gloved Hand Presses.” There were no vinyl flooring sections used in this study.
6. Only duplicate field fortified control samples were prepared for cotton gloves.

7. A separate set of alpha cellulose quality control samples were not prepared for each application. The low level field fortification samples were prepared on March 11, 2002 (day before first application) and the high level field fortification samples were prepared on March 15, 2002 (two days after the second application). Overall average field fortification recoveries of 85.9% for PYI and 75.2% for PBO were used to correct the alpha cellulose coupon residues from both applications.
8. The Study Report did not provide a justification for using bare hand palmar surface areas for transfer residues collected using cotton gloves.

COMPLIANCE:

A signed and dated Data Confidentiality statement was provided. A signed and dated GLP Compliance Statement was provided, however, it was noted that this study was not performed according to the US EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160). It was also noted that the data collection and study conduct were performed in the spirit of GLP. A Quality Assurance statement was provided in the Xenos Laboratories, Inc. Analytical Phase Report.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was conducted following Xenos and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 01-025-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation: An unidentified pre-fill batch fogger formulation containing 0.785% PY and 1.55% PBO as the active ingredients.

Batch # formulation: 0203-1

Formulation guarantee: McLaughlin Gormley King Company (MGK) Certificate of Analysis stated that the test substance contained 0.785% total pyrethrins and 1.55% PBO. The analysis was dated March 12, 2002.

CAS #(s): Pyrethrins: 8003-34-7 PBO: 51-03-6

Other Relevant Information: Toxcon ID No.: PY01 T006; MGK is the manufacturer of the test product.

2. Relevance of Test Material to Proposed Formulation(s):

The test product used for this study was a pre-fill batch formulation similar to that for an indoor fogger formulation developed by the McLaughlin Gormley King Company (MGK) intended for use in residential buildings. The name and label for this test product was not provided with the study.

B. Study Design:

There were three amendments to and one deviation from the study protocol. The amendments to the protocol involved the following: (1) due to small number of samples generated for the study, one set of field quality control samples will be sufficient; (2) a second fortification level for alpha cellulose was

prepared in order to cover a higher residue level to near the upper range which was expected to be found in the test samples; and (3) alpha cellulose field blanks prepared on March 11, 2002 were voided and new field blanks were prepared to reflect the increase in solvent volume that was used for the additional fortification level. The protocol deviation involved a transcription error which occurred during the production of the samples labels (FG12B and FG11B).

1. Site Description:

Test locations: Two test rooms (one spray room and one press room), referred to as simulated residential rooms, were located at the Toxcon Health Sciences Research Centre in Edmonton, Alberta, Canada. The rooms were prepared according to Toxcon SOP No. E-025: *Preparation of Test Rooms Prior to an Experiment*.

Meteorological Data: Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air change per hour (ACH), a temperature of $72 \pm 4^{\circ}\text{F}$ and a relative humidity of $50 \pm 10\%$.

Ventilation/Air-Filtration: The ventilation system for the spray room was turned off during application and for three hours after the application (with dampers closed). The dampers were opened after the three hours and for a 30 minute drying period, the room conditions were adjusted to reach the conditions prior to application.

2. Surface(s) Monitored:

Room(s) Monitored: Two test rooms, referred to as Simulated Residential Rooms (SRRs), were utilized in this study. One test room contained the application equipment (sprayboom) and the other room was used to perform the press procedures.

Room Size(s): The dimensions of both the spray room and the untreated rooms were 16 ft x 16 ft x 8 ft. Six wooden platforms (40" x 40" each) were placed in the center of the spray room.

Types of Surface(s): Carpet flooring

Surface Characteristics: Sections of carpet flooring were pinned onto sheets of plastic-covered plywood attached to the top of six wooden platforms. The carpet flooring specifications were provided in the protocol. The carpet was manufactured by KRAUS with the product name "Hyde Park." The carpet was made of saxony cut pile (100% BCF nylon) and was pre-treated with Master Guard™.

Areas sprayed and sampled: Two separate applications were done in the test room containing the sprayboom. For each application, a total of 66 new carpet flooring sections, cut into 12" x 8" sections, were pinned onto sheets of plastic-covered plywood attached to the top of six 40" x 40" wooden platforms (A total of 124 carpet flooring sections were used for this study). These flooring sections were treated along with deposition coupons (3" x 3"). A diagram of the deposition coupons and carpet flooring layout was provided on page 50 of the Study Report.

The surfaces monitored in this study were relevant to the proposed uses for this formulated product.

Other products used: N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment: Sprayboom

Application Regime: Each section of carpet flooring received one sprayboom run which was conducted in one Simulated Residential Room.

Application rate(s): An application rate was not provided in the Study Report. The application was based on the desired deposition rate of the test product onto the carpet flooring. For PY, the desired deposition rate was $3.96 \mu\text{g}/\text{cm}^2$ and for PBO, the desired deposition rate was $7.87 \mu\text{g}/\text{cm}^2$. Deposition rates were based on results of indoor PY and PBO total release fogger deposition studies. The sprayboom nozzle sweep speed required to obtain the desired deposition was calculated using the following equation: $U = [(Q_t)(F_a)(k_1)/(R)(n)(d)(10^{-6})]$, where U is the sprayboom nozzle sweep speed (cm/s), Q_t is the nozzle output rate (g/s), F_a is the fraction of pyrethrin in the formulation, R is the target deposition rate of PY ($\mu\text{g}/\text{cm}^2$), d is a fixed value representing the distance between nozzles (71.2 cm), n is the number of nozzles (5), and k_1 is a correction factor to account for formulation that is sprayed, but not deposited, on the test surface. The target speed was not provided in the Study Report but was reported to be documented in the raw data.

Equipment Calibration Procedures: The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. According to the Study Report, the operation of the sprayboom is described in detail in Toxcon SOP No. E-042 *Operation and Maintenance of the Whitmyre Application System for Pesticides (WASP)*. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. Therefore, the label recommended application method is not known.

Was total deposition measured? Yes, total deposition was measured using deposition coupons. The deposition coupons consisted of squares of alpha cellulose (3" x 3"). The coupons were backed with hexane-wiped heavy duty aluminum foil. The Study Report states that coupons were prepared according to Toxcon SOP No. M-015: *Preparation of Alpha Cellulose Deposition Coupon*. The alpha cellulose coupons were used to determine the application rate of the sprayboom equipment on two separate occasions (March 12, and March 13, 2002).

D. Sampling:

Surface Areas Sampled: Carpet flooring sections (12" x 8") were first treated with the test product. Three male subjects participated in the study. Hand presses were performed with both the left and right hand of the test subjects. The hand palmar surface areas of the subjects were measured using an ink image of the palm side of each hand. The hand palmar surface area acquisition methods were based on procedures described in Toxcon SOPs Nos. M-021 and M-022. The hand palmar surface areas for the left and the right hand of the first volunteer were 97.7 cm^2 and 89.2 cm^2 respectively, for the second volunteer 55.9 cm^2 and 61.0 cm^2 , respectively, and for the third volunteer 106.1 cm^2 and 108.4 cm^2 , respectively. The deposition coupons consisted of 3" x 3" squares of alpha cellulose with a surface area of 57.8 cm^2 .

Replicates per sampling interval: Bare hand presses resulted in a total of 4 dressing sponge samples (hand wipes) for each of the different consecutive press procedures (2, 4, 8, 16, and 32 presses) from 62 carpet flooring sections. Gloved hand presses resulted in a total of 4 cotton glove samples for each of the different consecutive press procedures (2, 4, 8, 16, and 32 presses) from 62 carpet flooring sections.

Number of sampling intervals: There was one sampling interval that occurred about 3.5 hours after application (i.e., 3 hours deposition period and 30 minute drying period).

Method and Equipment: Residue deposition was determined using alpha cellulose coupons. The transferability of PY and PBO was determined as a function of the different number of presses on new or the same treated area using bare hands (dressing sponges) and cotton gloved hands.

Sampling Procedure(s):

Deposition coupons -The alpha cellulose deposition coupons were used to determine the application rate of the sprayboom equipment on two separate occasions (March 12, and March 13, 2002). The deposition coupons were collected following a drying period after application of the test product. Disposable latex gloves were worn when the coupons were handled. The coupons were folded, so that the exposed side was on the inside, and then wrapped in hexane-wiped aluminum foil.

Bare hand residues- After the application (i.e., the second sprayboom run) and collection of the deposition coupons, the carpet flooring sections were taken to the hand press room. Each section of carpet flooring was placed in a hand press balance configuration. The transfer of residues was determined based on the applied force (~8 kg) and contact duration (~20 s). For the bare hand presses, four rounds of presses were performed for each number of presses (2, 4, 8, 16 or 32). Three male subjects performed the bare-hand presses. Hand presses were performed with both the left and right hand of the test subjects. One subject performed 2 (left hand) and 16 (right hand) presses and another subject performed 4 (left hand) and 8 (right hand) presses. The third subject performed 32 (right hand) presses. The first round of hand presses, involved a new piece of treated carpet flooring for each hand press (i.e., 8 consecutive presses required 8 previously untouched treated carpet flooring sections). Following the first round of hand presses, the subject's hand was cleaned with two hand wipes (dressing sponge) dampened with isopropyl alcohol and the dressing sponges were placed in a glass jar. The hand press procedure was repeated on the same area of each flooring section used for the first set of hand presses. This process was repeated three times.

Gloved hand residues- After the application (i.e., after the first sprayboom run) and collection of the deposition coupons, the carpet flooring sections were taken to the hand press room. Each section of carpet flooring was placed in a hand press balance configuration. The transfer of residues was determined based on the applied force (~8 kg) and contact duration (~20 s). For gloved hand presses, four rounds of presses were performed for each number of presses (2, 4, 8, 16 or 32). Three male subjects performed the gloved-hand presses. Hand presses were performed with both the left and right hand of the test subjects. One subject performed 2 (left hand) and 16 (right hand) presses and another subject performed 4 (left hand) and 8 (right hand) presses. The third subject performed 32 (right hand) presses. The first round of hand presses, involved a new piece of treated carpet flooring for each hand press (i.e., 8 consecutive presses required 8 previously untouched treated carpet flooring sections). Following the first round of hand presses, the gloves were collected, the subjects' hands were washed and new cotton gloves were put on and the hand press procedure was repeated on the same area of each flooring section used for the first set of hand presses. This process was repeated three times. The gloves were collected after each press procedure.

3. Sample Handling and Storage:

The deposition coupons (alpha cellulose samples) were wrapped in aluminum foil, labeled with unique identifications, placed in aluminum containers, and moved to freezer storage at less than -10°C within 3 hours of coupon retrieval. The dressing sponges and cotton gloves were placed in amber glass jars. All samples were stored in the dark at <-10°C until shipped for analysis. Samples were shipped to the analytical laboratory overnight in an insulated cooler with dry ice. The samples were received by Xenos Laboratories on March 20, 2002 and stored in a freezer until they were analyzed.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Extraction of Pyrethrin I (P-I), Cinerin I (C-I), Jasmolin I (J-I), and PBO residues was performed by sonication and mechanical shaking of the alpha cellulose coupons, dressing sponge samples, and cotton gloves at room temperature with ethyl acetate. Extraction was performed and the ethyl acetate was taken to dryness by rotary evaporation. The sample extracts were made up to an appropriate volume in acetonitrile and analyzed for PBO using HPLC/Fluorescence. An aliquot of the acetonitrile solution was taken to dryness and reconstituted in toluene and analyzed for PYI using GC/ECD. For cotton gloves and dressing sponges, further clean up with Isolute silica SPE was conducted prior to analysis.

B. Detection methods:

A gas chromatograph/ electron capture detector was used for the analysis of PYI and a Shimadzu HPLC system was used for the analysis of PBO. The method measured three Pyrethrin esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I), and PBO. See Table 1 for specific conditions.

Table1. Gas Chromatographic / Electron Capture Detector and HPLC Conditions

Gas Chromatographic Conditions	
GC Column	SPB-1, 30 m x 0.32 mm ID, 0.25 .m film
Temperatures	Inlet: Initial - 120°C (hold 0.10 min) Program - 120-280°C @ 20°C/min (hold 10 min) Column: Initial - 90°C (hold 2.0 min) Prog 1 - 90-140°C @ 20°C/min Prog 2 - 140-210°C @ 2.5°C/min Prog 3 - 210-300°C @ 50°C/min (hold 5 min) Detector: 330°C
Carrier Gas Flow Rate	5.4 mL/min
Injection Volume	2.0 .L (splitless)
Injection Rate	0.5 .L/sec on column
Approximate Retention Times	C-I ~ 26.9 min, J-I ~ 29.5 min, P-I ~ 30.3 min
Liquid Chromatographic Conditions	

Column	Zorbax Rx-C8, 4.6 x 250 mm
Temperature	30°C
Mobile Phase	Isocratic: 70% acetonitrile 30% water
Flow Rate	1.0 mL/min
Injection Volume	20 μ L
Fluorescence Detection	Excitation: 288 nm, Emission: 345 nm
Approximate Retention Time	PBO: ~ 8.4 min

D. Method Validation:

The analytical methods were validated in a previous study, prior to initiation of the field phase of this study to determine the integrity and efficiency of Xenos' Analytical Method XAM-66 which was used for the analysis of the three Pyrethrin esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I) and PBO residues in/on alpha cellulose coupons, dressing sponges and cotton glove samples.

The Study Report provides validation data for the limits of quantitation (LOQ) which were taken from Xenos report XEN01-12. Method validation recoveries were not provided in the study. However, the validated limits of quantitation (LOQ) for PYI, PY and PBO residues on alpha cellulose, cotton gloves, and dressing sponges are summarized in Table 2. According to the Study Report, it was necessary to further validate the method at higher levels of fortification for cotton gloves and dressing sponges because of the high levels of residues found in the study samples. Recoveries were above 90% for all of these fortified samples.

Table2. Validated LOQs¹

Matrix	Formulation	LOQ (μ g)		
		PYI	PY	PBO
Alpha Cellulose	10.0 mg	44.0	78.4	158
Cotton Gloves	200 μ g	0.880	1.57	3.16
Dressing Sponges	100 μ g	0.440	0.784	158

¹ Validation data from Xenos report XEN01-12.

Instrument performance and calibration: The GC/ECD and HPLC/Fluorescence responses were determined for a series of calibration standards. The GC/ECD calibration solutions were prepared from the formulation by dilution in toluene. A total of 5 concentrations were used to calibrate the system: 0.005, 0.010, 0.020, 0.030, and 0.040 μ g/L. The HPLC/Fluorescence calibration solutions were prepared from the formulation by dilution in acetonitrile. A total of 5 concentrations were used to calibrate the system: 0.010, 0.020, 0.040, 0.060, and 0.080 μ g/L. The demonstrated R² values for PYI and PBO were 0.9965 and 0.9998, respectively, which met the SOP criteria of being equal to or greater than 0.98.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control samples were fortified with the formulated product, prior to extraction, within the concentration ranges expected from the field samples. According to the study protocol, average laboratory recoveries in the

range of 70 to 120% with a coefficient of variation of +/- 20% were considered acceptable for the study. Concurrent laboratory control samples were prepared and run for the alpha cellulose coupons, the dressing sponges and the cotton gloves. Results from the laboratory fortified samples are summarized in Table 3 and they support the performance of the method throughout the analytical phase of the study.

For the alpha cellulose fortified laboratory controls, samples were fortified at the LOQ, 2X the LOQ, 5X the LOQ, 7.5X the LOQ, 10X the LOQ and 20X the LOQ for PYI and PBO. The percent recoveries ranged from 88% to 107% for PYI and from 68.1% to 111% for PBO. The overall average recoveries were $99.1 \pm 6.1\%$ for PYI and $97.2 \pm 10.3\%$ for PBO.

For the dressing sponge fortified laboratory controls, samples were fortified at the LOQ, 10X the LOQ, 50X the LOQ, 100X the LOQ, and 1000X the LOQ. The percent recoveries ranged from 80% to 106% for PYI and from 84.4% to 109% for PBO. The overall average recoveries were $94.4 \pm 10\%$ for PYI and $97.9 \pm 6.0\%$ for PBO.

For the cotton glove fortified laboratory controls, samples were fortified at the LOQ, 5X the LOQ, 35X the LOQ, 125X the LOQ, and 250X the LOQ for PYI and PBO. The percent recoveries ranged from 74.4% to 114% for PYI and from 77.9% to 104% for PBO. The overall average recoveries were $96.1 \pm 17.8\%$ for PYI and $95.3 \pm 7.3\%$ for PBO.

Table3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (μg) ¹		No. of Samples	Average Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO		PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Alpha Cellulose	44.1	155	6	97.1	94.8	99.1	97.2	6.14	10.3	6.2	10.6
	88.2	310	1	94.8	95.8						
	221	775	1	100	100						
	331	1163	1	98.5	95.2						
	441	1550	2	106	101						
	882	3100	1	101	104						
Dressing Sponge	0.441	1.55	4	87.2	97.2	94.4	97.9	10	6	10.5	6.1
	4.41	15.5	1	80	97.9						
	22.1	77.5	1	106	97.2						
	44.1	155	1	98.1	98.4						
	441	1550	3	104	98.3						
Cotton Glove	0.882	3.10	4	78.3	95.7	96.1	95.3	17.8	7.3	18.5	7.6
	4.41	15.5	1	112	93.7						
	30.9	109	1	85.0	92.0						
	110	388	1	114	94.0						
	221	775	3	112	97.1						

1 Alpha cellulose LOQ for PYI = 44.1 $\mu\text{g}/\text{sample}$ and the LOQ for PBO = 155 $\mu\text{g}/\text{sample}$.

Dressing sponge LOQ for PYI = 0.441 µg/sample and the LOQ for PBO = 1.55µg/sample.

Cotton glove LOQ for PYI = 0.882 µg/sample and the LOQ for PBO = 3.10µg/sample.

Fortification levels are at 1X, 2X, 5X, 7.5X, 10X, and 20X the LOQ for alpha cellulose, 1X, 10X, 50X, 100X, and 1000X the LOQ for dressing sponges, and 1X, 5X, 35X, 125X, and 250X the LOQ for cotton gloves.

Field Fortification: Alpha cellulose coupon field control samples were fortified with the formulated test product at 3.25X and 6.5X the LOQ. Dressing sponge field control samples were fortified with the formulated test product at 6.5X and 65X the LOQ. Cotton glove field control samples were fortified with the formulated test product at 3.25X and 32.5X the LOQ. These field fortified control samples were exposed for the same amount of time and under the same conditions as the test samples. They were also stored and analyzed with the test samples. Alpha cellulose and dressing sponge field fortified samples were prepared in triplicate and cotton glove field fortified samples were prepared in duplicate. Field fortification results are summarized in Table 4.

The low level alpha cellulose field fortified samples were prepared a day before the first application (March 11, 2002) and the high level fortification samples were prepared two days after the second application (March 15, 2002). The average recovery of the low level spike for PYI was 90.4% versus 81.5% at the high level. The average recovery of the low level spike for PBO was 76.0% versus 74.5% at the high level. The overall average recoveries for PYI and for PBO were $85.9 \pm 9.3\%$ and $75.2 \pm 3.5\%$, respectively.

For dressing sponge field fortified control samples, the average recovery of the low level spike for PYI was 107% versus 104% at the high level. The average recovery of the low level spike for PBO was 106% versus 99.5% at the high level. The overall average recoveries were $106 \pm 6.8\%$ for PYI and $103 \pm 4.9\%$ for PBO.

For cotton glove field fortified control samples, the average recovery of the low level spike for PYI was 98.1% versus 104% at the high level. The average recovery of the low level spike for PBO was 104% versus 96.8% at the high level. Overall average recoveries were $99.5 \pm 9.8\%$ for PYI and $102 \pm 4.4\%$ for PBO.

Table 4 Summary of Field Fortification Recoveries

Matrix	Fortification Level (µg) ¹		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Alpha Cellulose	143	504	114	105	79.2	80.4	85.9	75.2	9.3	3.5	10.8	4.6
			126	368	88.1	73.1						
			148	375	104	74.4						
	287	1008	232	754	80.8	74.8						
			226	713	78.9	70.7						
			243	787	84.8	78.1						
Dressing Sponge	2.87	10.1	2.97	10.7	104	106	106	103	6.8	4.9	6.4	4.8
			3.26	11.1	114	110						

	Fortification Level (µg) ¹		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	28.7	101	2.96	10.4	103	103						
			27.2	96.3	94.9	95.6						
			32.1	103	112	102						
			30.4	102	106	101						
Cotton Glove	2.87	10.1	3.06	10.8	107	107	99.5	102	9.8	4.4	9.9	4.4
			2.44	10.1	85.3	100						
	28.7	101	29.3	104	102	104						
			29.9	97.5	104	96.8						

1 Alpha cellulose LOQ for PYI = 44.1 µg/sample and the LOQ for PBO = 155 µg/sample.
Dressing sponge LOQ for PYI = 0.441 µg/sample and the LOQ for PBO = 1.55 µg/sample.
Cotton glove LOQ for PYI = 0.882 µg/sample and the LOQ for PBO = 3.10 µg/sample.
Fortification was at 3.25X and 6.5X the LOQ for alpha cellulose; 6.5X and 65X the LOQ for dressing sponges and 3.25X and 32.5X the LOQ for cotton glove fortified control samples.

Control Samples: Six alpha cellulose coupon samples were prepared as laboratory controls and duplicate alpha cellulose coupon samples were prepared as field controls. Four control samples were prepared as laboratory controls for both dressing sponges and cotton gloves. Duplicate control samples were prepared as field controls for both dressing sponges and cotton gloves. For preparation of blank samples, a volume of solvent approximately equivalent to the largest volume of solution used in fortification was added to each blank sample.

For the laboratory blanks, there were no detectable levels of PYI or PBO residues in the alpha cellulose coupons and cotton gloves. The results for the dressing sponges and cotton gloves showed detectable residue levels of PYI and PBO below the limit of quantification (LOQ).

For the field blanks, there were no detectable PYI or PBO residues in the alpha cellulose coupons. The results for the dressing sponges and cotton gloves showed detectable residue levels of PYI and PBO below the limit of quantification (LOQ).

Storage Stability: The field fortified samples for alpha cellulose coupons were analyzed after a maximum period of 29 days in frozen storage. The field fortified samples for the dressing sponges and cotton gloves were analyzed after a maximum period of 49 and 36 days in frozen storage, respectively. All study samples were analyzed within a similar time frame. The field fortification results, discussed above, for all three matrices support the stability of the residues for each time period.

V. RESULTS

Residues were reported for both PYI and PBO, as well as PY, which is total pyrethrin calculated from the PYI data by using a conversion factor (1.78 for test product batch # 0203-1). This conversion factor was derived from the percentages of total pyrethrins and PYI in the formulated product. Versar corrected alpha cellulose coupon residue data for field fortification recoveries below 90%. The Study Report did not correct for field fortification recoveries.

A. Alpha Cellulose and Deposition of Formulation:

The alpha cellulose coupons were used to determine the application rate of the sprayboom for the two applications. According to the study report the average application rate on March 12, 2002 was $4.16 \mu\text{g}/\text{cm}^2$ PY and $8.82 \mu\text{g}/\text{cm}^2$ PBO. On March 13, 2002 the average application rate was $4.57 \mu\text{g}/\text{cm}^2$ PY and $9.28 \mu\text{g}/\text{cm}^2$ PBO. Versar corrected PYI and PBO residues for low field fortification recoveries. Low level field fortification samples were prepared on March 11, 2002 (one day prior to first application) and the high level field fortification samples were prepared on March 15, 2002 (two days after the second application). Therefore, the overall average field fortification recoveries of 85.9% and 75.2% for PYI and PBO were used to correct alpha cellulose coupon residues from both applications. For the March 12, 2002 application, the resulting mean corrected residues for PY and PBO were $4.84 \pm 1.13 \mu\text{g}/\text{cm}^2$ and $11.7 \pm 2.27 \mu\text{g}/\text{cm}^2$, respectively. The achieved deposition rate is estimated to be 122% of the target deposition rate for PY and 149% of the target deposition rate for PBO. For the March 13, 2002 application, the resulting mean corrected residues for PY and PBO were $5.32 \pm 0.90 \mu\text{g}/\text{cm}^2$ and $12.3 \pm 2.00 \mu\text{g}/\text{cm}^2$, respectively. The achieved deposition rate is estimated to be 134% of the target deposition rate for PY and 157% of the target deposition rate for PBO.

B. Bare Hand Residues:

The degree of transfer of PY and PBO residues from carpet flooring was carried out by using bare hands on the treated surfaces and applying multiple presses on a new or the same treated area. Total hand residues were calculated by the Study Report for each hand of the test subject after four rounds of 2, 4, 8, 16, and 32 consecutive bare hand presses on either a new piece of treated carpet flooring, or on the same piece within the same area of carpet flooring. Following each round of hand pressing, residues which were transferred from the treated flooring sections to the palm of the hand were collected using an isopropyl alcohol based dressing sponge wipe procedure. Residues were reported for PY and PBO as $\mu\text{g}/\text{sample}$ and ng/cm^2 . The overall average field fortification recoveries for the dressing sponges were >90% for both PYI and PBO. Therefore, the dressing sponge residue data did not require correction for field fortification recoveries. PY is total pyrethrin calculated by using a conversion factor (1.78 for test product batch # 0203-1) derived from the percentages of total pyrethrins and PYI in the formulated product. The Study Report provided residue data as $\mu\text{g}/\text{sample}$ and ng/cm^2 . Versar calculated transfer residue data as $\mu\text{g}/\text{cm}^2$. Summaries of Versar's calculated PY and PBO transfer residues resulting from multiple bare hand presses on carpet flooring are provided in Table 5.

Bare hand transfer residues for the different number of presses for each of the four rounds ranged from $0.118 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $3.69 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PY and from $0.184 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $7.08 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PBO. The percent of residue on the dressing sponges after bare hand contact with treated carpet flooring surfaces was calculated as the ratio of the amount of residue present on the dressing sponges divided by the average corrected residue found on the alpha cellulose coupons. The overall average uncorrected residues found on the coupons from the March 13, 2002 application were reported to be $4.57 \pm 0.771 \mu\text{g}/\text{cm}^2$ for PY and $9.28 \pm 1.51 \mu\text{g}/\text{cm}^2$ for PBO. When corrected for the field fortification recoveries, the coupon residues averaged $5.32 \pm 0.90 \mu\text{g}/\text{cm}^2$ for PY and $12.3 \pm 2.00 \mu\text{g}/\text{cm}^2$ for PBO. Versar calculated the percentages of PY and PBO residues transferred from carpet surfaces for each of the total number of multiple presses for the four rounds of presses and for each of the individual presses for the four rounds. These percentages were provided in Table 5. A total of 69.4% of the surface concentration of PY and 57.5% of the surface concentration of PBO was transferred to the bare hand after contact with 32

previously untouched treated carpet surfaces. After 2 presses on the fourth round, only 2.2% of PY and 1.5% of PBO was transferred to the bare hand.

C. Glove Coupon Residues

The overall average field fortification recoveries for the cotton gloves were >90% for both PYI and PBO. Therefore, the cotton glove residue data did not require correction for field fortification recoveries. PY is total pyrethrin calculated by using a conversion factor (1.78 for test product batch # 0203-1) derived from the percentages of total pyrethrins and PYI in the formulated product. The degree of transfer of PY and PBO residues from carpet flooring was carried out by using gloved hands on the treated surfaces and applying multiple presses on a new or the same treated area. Four rounds of 2, 4, 8, 16, and 32 presses were used. The Study Report provided residue data as $\mu\text{g}/\text{sample}$ and ng/cm^2 . Versar calculated transfer residue data as $\mu\text{g}/\text{cm}^2$. Summaries of Versar's calculated PY and PBO transfer residues resulting from multiple presses on carpet flooring are provided in Table 6.

Glove transfer residues for the different number of presses for each of the four rounds ranged from $0.144 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $3.07 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PY and from $0.245 \mu\text{g}/\text{cm}^2$ (4th round, after 2 presses) to $5.89 \mu\text{g}/\text{cm}^2$ (1st round, after 32 presses) for PBO.

The percent of residue on the cotton gloves after contact with treated carpet flooring surfaces was calculated as the ratio of the amount of residue present on the gloves divided by the average corrected residue found on the alpha cellulose coupons. The overall average uncorrected residues found on the coupons from the March 12, 2002 application were reported to be $4.16 \pm 0.969 \mu\text{g}/\text{cm}^2$ for PY and $8.82 \pm 1.71 \mu\text{g}/\text{cm}^2$ for PBO. When corrected for the field fortification recoveries, the coupon residues averaged $4.84 \pm 1.13 \mu\text{g}/\text{cm}^2$ for PY and $11.7 \pm 2.27 \mu\text{g}/\text{cm}^2$ for PBO. Versar calculated the percentages of PY and PBO residues transferred from carpet surfaces for each of the total number of multiple presses for the four rounds of presses and for each of the individual presses for the four rounds. These percentages were provided in Table 6. A total of 63.4% of the surface concentration of PY and 50.4% of the surface concentration of PBO was transferred to the gloved hand after contact with 32 previously untouched treated carpet surfaces. After 2 presses on the fourth round, only 3.0% of PY and 2.1% of PBO was transferred to the gloved hand.

VI. CONCLUSION

The transfer of PY and PBO residues from treated carpet flooring to bare hands and cotton gloved hands following multiple presses on new or the same treated area was measured. The results of this study indicate that the amount of residue per press of both PY and PBO transferred from a carpet flooring surface to bare hands or cotton gloves following four rounds of 2 to 32 hand presses initially increased and then decreased as the number of presses increased. The residues of PY and PBO was highest in round 1 and then decreased with every successive round of presses.

No noticeable differences were seen between the percent transfer of PY or PBO to the bare or gloved hand.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and a label was not provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- On page 18 of the Study Report, in the Methods section (IX), the study author listed 4 phases of the study. Phase III was said to be “the bare hand press exposure and the indoor roller transferability...” Indoor roller transferability was not a part of this study.
- Table 1 on page 36 of the Study Report is titled “Assignment of Treatments and Treated Vinyl Flooring Sections for Bare and Gloved Hand Presses.” There were no vinyl flooring sections used in this study.
- Only duplicate field fortified control samples were prepared for cotton gloves.
- A separate set of alpha cellulose quality control samples were not prepared for each application. The low level field fortification samples were prepared on March 11, 2002 (day before first application) and the high level field fortification samples were prepared on March 15, 2002 (two days after the second application). Overall average field fortification recoveries of 85.9% for PYI and 75.2% for PBO were used to correct the alpha cellulose coupon residues from both applications.
- The Study Report did not provide a justification for using bare hand palmar surface areas for transfer residues collected using cotton gloves.

Table 5. Summary of PY and PBO Bare Hand Press Results on Carpet Flooring Following Multiple Presses

Rounds ^a	# of Carpet Sections Pressed	Measured Residue (µg/sample)		Glove Surface Area (cm ²) ^b	Residue by # of Presses (µg/cm ²) ^c			% of Application by # of Presses ^e		Residue per Press (µg/cm ²) ^f		% of Application per Press	
		PYI	PBO		PYI	PY ^d	PBO	PY	PBO	PY	PBO	PY	PBO
1	2	2.42	41.1	97.7	0.0229	0.235	0.421	4.42	3.42	0.118	0.210	2.21	1.71
	4	23.0	72.3	55.9	0.411	0.732	1.29	13.8	10.5	0.183	0.323	3.44	2.63
	8	18.8	130	61.0	0.308	0.549	2.13	10.3	17.3	0.069	0.266	1.29	2.17
	16	86.0	314	89.2	0.964	1.72	3.52	32.3	28.6	0.107	0.220	2.02	1.79
	32	225	767	108.4	2.08	3.69	7.08	69.4	57.5	0.115	0.221	2.17	1.80
2	2	8.14	23.7	97.7	0.083	0.148	0.243	2.79	1.97	0.074	0.121	1.39	0.99
	4	12.9	36.8	55.9	0.231	0.411	0.658	7.72	5.35	0.103	0.165	1.93	1.34
	8	24.5	77.5	61.0	0.402	0.715	1.27	13.4	10.3	0.089	0.159	1.68	1.29
	16	58.7	194	89.2	0.658	1.17	2.17	22.0	17.7	0.073	0.136	1.38	1.11
	32	123	415	108.4	1.13	2.02	3.83	38.0	31.1	0.063	0.120	1.19	0.97
3	2	9.51	35.1	97.7	0.097	0.173	0.359	3.26	2.92	0.087	0.180	1.63	1.46
	4	9.36	29.9	55.9	0.167	0.298	0.535	5.60	4.35	0.075	0.134	1.40	1.09
	8	22.2	71.4	61.0	0.364	0.648	1.17	12.2	9.52	0.081	0.146	1.52	1.19
	16	53.1	164	89.2	0.595	1.06	1.84	19.9	14.9	0.066	0.115	1.24	0.93
	32	124	415	108.4	1.14	2.04	3.83	38.3	31.1	0.064	0.120	1.20	0.97
4	2	6.45	18.0	97.7	0.066	0.118	0.184	2.21	1.50	0.059	0.092	1.10	0.75
	4	9.33	29.6	55.9	0.167	0.297	0.530	5.58	4.31	0.074	0.132	1.40	1.08
	8	20.6	63.7	61.0	0.338	0.601	1.04	11.3	8.49	0.075	0.131	1.41	1.06
	16	47.9	149	89.2	0.537	0.956	1.67	18.0	13.6	0.060	0.104	1.12	0.85
	32	106	359	108.4	0.978	1.74	3.31	32.7	26.9	0.054	0.103	1.02	0.84

- a For the first round of presses a new area of formulation treated flooring section was used. For the second round of presses, the same hand was used on the same area of each previously used flooring section for a repeat of exposure.
- b PY is total pyrethrin calculated by using a conversion factor (1.78 for test product batch # 0203-1) derived from the percentages of total pyrethrins and PYI in the formulated product.
- c No correction needed since field fortification recoveries were above 90% (PY = 99.6 and PBO=102%).
- d Based on the hand palmer surface area measurements.
- e Calculated as the ratio of the amount of residue present on the dressing sponge divided by the overall average corrected residue found on the alpha cellulose coupons for March 13, 2002 (5.32 .g/cm² for PY and 12.3 .g/cm² for PBO).
- f Calculated by dividing the average residue by number of presses by the number of presses.

Table 6. Summary of PY and PBO Gloved Hand Press Results on Carpet Flooring Following Multiple Presses

Rounds ^a	# of Carpet Sections Presses	Measured Residue (µg/sample)		Glove Surface Area (cm ²) ^b	Corrected Residue by # of Presses (µg/cm ²) ^c			% of Application by # of Presses ^e		Residue per Press (µg/cm ²) ^f		% of Application per Press	
		PYI	PBO		PYI	PY ^d	PBO	PY	PBO	PY	PBO	PY	PBO
1	2	11.2	36.5	97.7	0.115	0.204	0.374	4.22	3.19	0.102	0.187	2.11	1.60
	4	lost	lost	55.9	lost	lost	lost	lost	lost	lost	lost	lost	lost
	8	44.0	132	61.0	0.721	1.28	2.16	26.5	18.5	0.160	0.270	3.32	2.31
	16	83.9	255	89.2	0.941	1.67	2.86	34.6	24.4	0.105	0.179	2.16	1.53
	32	187	639	108.4	1.73	3.07	5.89	63.4	50.4	0.096	0.184	1.98	1.57
2	2	9.70	31.4	97.7	0.099	0.177	0.321	3.65	2.75	0.088	0.161	1.83	1.37
	4	21.3	68.4	55.9	0.381	0.678	1.22	14.0	10.5	0.170	0.306	3.50	2.61
	8	38.6	117	61.0	0.633	1.13	1.92	23.3	16.4	0.141	0.240	2.91	2.05
	16	82.3	243	89.2	0.923	1.64	2.72	33.9	23.3	0.103	0.170	2.12	1.46
	32	182	543	108.4	1.68	2.99	5.01	61.7	42.8	0.093	0.157	1.93	1.34
3	2	10.0	30.8	97.7	0.102	0.182	0.315	3.75	2.69	0.091	0.158	1.88	1.35
	4	16.3	47.5	55.9	0.292	0.519	0.850	10.7	7.26	0.130	0.212	2.68	1.82
	8	38.2	111	61.0	0.626	1.11	1.82	23.0	15.6	0.139	0.227	2.88	1.94
	16	73.7	220	89.2	0.826	1.47	2.47	30.4	21.1	0.092	0.154	1.90	1.32
	32	171	535	108.4	1.58	2.81	4.94	58.0	42.2	0.088	0.154	1.81	1.32
4	2	7.93	23.9	97.7	0.081	0.144	0.245	2.99	2.09	0.072	0.122	1.49	1.05
	4	12.2	34.8	55.9	0.218	0.388	0.623	8.03	5.32	0.097	0.156	2.01	1.33
	8	36.7	108	61.0	0.602	1.07	1.77	22.1	15.1	0.134	0.221	2.77	1.89
	16	65.7	205	89.2	0.737	1.31	2.30	27.1	19.6	0.082	0.144	1.69	1.23
	32	162	480	108.4	1.49	2.66	4.43	55.0	37.8	0.083	0.138	1.72	1.18

- a For the first round of presses a new area of formulation treated flooring section was used. For the second round of presses, a new glove is placed on the same hand and the gloved hand press procedure was repeated on the same area of each previously used flooring section for a repeat of exposure. This process was repeated three additional times for each section of flooring for a total of four rounds.
- b Hand palmer surface area measurements.
- c Converted from .g/sample to $\mu\text{g}/\text{cm}^2$ based on hand palmer surface area measurements.
- d PY is total pyrethrin calculated by using a conversion factor (1.78 for test product batch # 0203-1) derived from the percentages of total pyrethrins and PYI in the formulated product.
- e Calculated as the ratio of the amount of residue present on the cotton gloves divided by the average corrected residue found on the alpha cellulose coupons from March 12, 2002 ($4.84 \text{ .g}/\text{cm}^2$ for PY and $11.7 \text{ .g}/\text{cm}^2$ for PBO).
- f Calculated by dividing the average residue by number of presses by the number of presses.

APPENDIX A

Compliance Checklist for “*Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses*”

Compliance Checklist for "Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Carpet Flooring Treated with a Fogger Formulation to Bare and Cotton Gloved Hands Following Multiple Hand Presses"

**GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION**

1. *The test substance must be the typical end use product of the active ingredient.* It is unclear if this criterion was met. The test product was an unidentified product and no label was provided.
2. *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case_by case basis.* This criterion does not appear to apply to this study.
3. *Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions.* This criterion was met.
4. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* This criterion was not met. Application was based on a target deposition rate, determined in another study.
5. *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study. Two sprayboom runs were performed on two separate days and two separate batches of carpet sections in order to generate sufficient carpet-treated flooring sections.
6. *Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials).* This criterion does not apply to this study. The objective was to determine residue transfer to bare hands and gloved hands from contact with a treated carpet flooring section.
7. *Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs.* This criterion does not apply to this study.
8. *Triplicate, randomly collected samples should be collected at each sampling interval for each surface type.* This criterion was met. Samples were taken of dressing sponges and cotton gloves. Four dressing sponge and cotton glove sample replicates were collected. The randomness of the carpet flooring sections used were discussed in the Study Report.
9. *Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces.* This criterion was met. Samples were collected using dressing sponge and cotton glove samples.

10. Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided. This criterion was met. Samples were stored in a manner that minimized deterioration and loss of analytes. Alpha cellulose field fortification samples were analyzed after a period of 29 days to ensure storage stability. Dressing sponge and cotton glove field fortification samples were analyzed after a period of 49 and 36 days, respectively.

11. Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided. This criterion was met.

12. Raw residue data must be corrected if appropriate recovery values are less than 90 percent. This criterion was not met. Alpha cellulose coupon residue data were not corrected for an overall average field fortification recovery of 85.9% for PYI and 75.2% for PBO. Dressing sponge and cotton glove residue data did not require correction for field fortification recoveries <90%.

13. Indoor surface residues should be reported as mg per m² or cm² of surface sampled. Distributional data should be reported, to the extent possible. These criteria were partially met. Residues from sponge and cotton glove press samples were reported as µg/sample and ng/cm².

14. Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval. This criterion does not apply to this study.